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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Trevor Morgan

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7590

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EXAMINER

TSAY, MARSHA M

ART UNIT

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/542,115	<b>Applicant(s)</b> MORGAN ET AL.	
	<b>Examiner</b> Marsha M. Tsay	<b>Art Unit</b> 1656	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 23 July 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some    \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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This Office action is in response to Applicants' remarks received July 23, 2007. Claims 1-21 are pending and currently under examination.

Applicants' arguments have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous Office actions are hereby withdrawn.

Priority: The priority date is February 21, 2003.

### **Objection and Rejections**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2-3 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 2-3 recite the fat content in the film is below 20% and 18% by weight, respectively. The claims are dependent on claim 1, which recites an extrudable collagen gel having a fat content. Claims 2-3 do not recite a lower limit for the fat content, therefore, the fat content can include 0%, which is confusing since claim 1 recites the gel has a fat content.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-9, 13, 15, 17-21 remain rejected under 35 U.S.C. 102(b) as being anticipated by Eckmayer et al. (US 6482240; IDS). Eckmayer et al. teach collagen membranes formed from porcine skins are enzymatically defatted, ground into a gel-like mass, extruded and dried into a collagen membrane (col. 2 lines 59-67; claim 1). Eckmayer et al. teach the collagen membranes can encompass films (col. 1 lines 13). In example 1, Eckmayer et al. teach a method of producing a porcine collagen film comprising defatting porcine skins by mechanical means (col. 4 line 64), forming a gel-like fluid mass (col. 8 lines 17), and extruding the gel to form a film and/or membrane (col. 10 line 1) (claims 19-20). Eckmayer et al. teach the collagen film can be used as a tube and/or net to wrap around ham (col. 12 lines 16-25; claims 18, 21). The porcine collagen film of Eckmayer et al. has a fat content of about 10% or less by dry weight of the collagen membrane (col. 16 lines 3-6; claims 1, 2-3, 4-6, 7-9, 17). Claims 4-6 are indefinite; therefore, it is believed that the Eckmayer et al. reference meets the limitations of these claims. Additionally, Eckmayer et al. teach the content of the gel-like fluid mass can include glycerol (humectant) and sorbitol (coagulating agent) (col. 8 lines 40-45; claims 13, 15).

Although Eckmayer et al. do not specifically teach the limitation of a wet tear strength greater than 300 gf/mm, this element is anticipated by Eckmayer et al. because Eckmayer et al. teach an extruded porcine collagen film and for a collagen film to be extruded, it must meet the

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limitations of instant claim 1 and therefore, should inherently have a wet tear strength in the extrusion direction greater than 300 gf/mm (claim 17).

In their remarks, Applicants assert Eckmayer et al. specifically describe the production of collagen membranes from porcine rinds. The basis of the present invention is in the discovery that the use of sow collagen results in collagen films, which have superior mechanical properties. Applicants further assert Eckmayer et al. is silent in regard to the use of sow collagen in the preparation of a collagen film. Applicants' arguments have been fully considered but they are not persuasive.

The use of open language "consists essentially of" to describe compositions allows room for unspecified components as long as they do not materially affect the basic and novel characteristics of the claimed invention. Applicants assert that Eckmayer et al. teach the production of collagen membranes from porcine rinds. The Merriam-Webster dictionary definition of sow is a female pig (M-W reference sheet). It is known in the art that porcine rind is porcine skin (Eckmayer et al. col. 2 line 54) and that mammalian skin inherently comprises collagen. Eckmayer et al. describe the use of porcine skin, which would inherently include skin from sows. Therefore, the collagen membranes of Eckmayer et al. do consist essentially of sow collagen. Eckmayer et al. also teach that the collagen membrane can be used to wrap around a food product, i.e. ham, therefore; one of ordinary skill would recognize that the collagen "membrane" of Eckmayer is equivalent to a "film" or "casing", even if not explicitly stated. For these reasons, the instant claims remain rejected under 35 U.S.C. 102(b) as being anticipated by Eckmayer et al.

Claims 1-21 are rejected under 35 U.S.C. 102(e) as being anticipated by Morgan et al. (US 20050031741).

The applied reference has 2 common inventors with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

The term film, as used in the instant invention, is given its broadest reasonable interpretation and is determined to be functionally equivalent to the casing of Morgan et al. Further, it is noted that the instant specification appears to use the terms film and casing interchangeably.

Morgan et al. teach collagen casings or film made from an extrudable collagen gel, wherein the collagen is porcine collagen (p. 1 [0001]-[0002]). In working examples 3-4, Morgan et al. teach a porcine collagen film was prepared from an extrudable porcine collagen gel, having a weight ratio of collagen to fat of around 30:1 (p. 4 [0059]; claims 1, 4-6, 17). The table in paragraph [0062]) indicates a fat percentage of 0.31% and 0.19% for examples 3 and 4, respectively (p. 4; claims 1-3). The porcine collagen casing and/or film in example 20 comprises 6.0% of caprine (goat) collagen on a dry weight basis (p. 12; claims 7-8). Morgan et al. also teach that the collagen properties of the casings can be varied by mixing collagen derived from young pigs (4 mos. old) and older pigs (3 yrs. old) in ratios of 0:100 to 100:0 (p. 2 [0019]; claim

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9). In example 12, Morgan et al. teach a porcine collagen casing with a humectant (i.e. glycerol) level of 21.5% on a dry weight basis (p. 8-9; claims 13-14). The collagen casing in example 16 comprises propylene glycol alginate (p. 10; claims 10-12). In example 9, Morgan et al. teach the porcine casing further comprises glutaraldehyde (p. 6 [0128]; claim 15). Also, the collagen casing has a collagen solids content of 7% (p. 13-14; claim 16). In example 1-4, Morgan et al. teach the porcine collagen casings were used to make sausages (p. 3-4; claim 21). The casing of Morgan et al. can also be used to make edible string and/or netting (p. 2 [0022]; claim 18). Further, Morgan et al. teach a method of producing an extruded porcine collagen film from sow collagen comprising soaking sow skins, removing fat by a fleshing machine (p. 3 [0032]), forming an extrudable gel from the sow skins by blending and disintegrating porcine skin (p. 3 [0039]), and extruding the gel to form a case and/or a film (p. 3 [0040]-[0045]) (claims 19-20). Although Morgan et al. do not specifically teach the limitation of a wet tear strength greater than 300 gf/mm, this element is anticipated by Morgan et al. because Morgan et al. teach an extruded porcine collagen film that meets the limitations of instant claim 1 and therefore, should inherently have a wet tear strength in the extrusion direction greater than 300 gf/mm (claim 17).

In their remarks, Applicants assert that Morgan et al. discuss tubular casings, whereas the present claims are directed to an extruded film. Applicants further assert the Examiner has determined the term “film” to be functionally equivalent to the term “casing”, which is discussed in the Morgan et al. reference. According to Applicants’, the terms “casing” and “film” are terms of art which are well in the industry and have well-established and quite different meanings. Applicants assert that it can be appreciated that an extruded casing is tubular, whereas

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an extruded film is planar. There is no disclosure in the Morgan et al. reference of the production of a non-tubular film and conversely, there is no disclosure in the present application that the film may be converted into a tubular casing. Applicants' arguments have been fully considered but they are not persuasive.

As noted above and in the previous Office action, the instant specification appears to use the terms film and casing interchangeably (Specification p. 2, 3), as does the Morgan et al. reference (p. 1 [0002], [0008]). It should also be noted that the instant claims are drawn to an extruded porcine collagen film made from an extrudable collagen gel having a fat content, wherein the collagen content of the film consists essentially of sow collagen. There is no limitation in the instant claims that restrict the instant invention to a non-tubular film. Further, the specification discloses that the instant porcine collagen film can be used to wrap a pork product (p. 7), which can encompass a sausage. Morgan et al. teach that the porcine collagen casing can be used to wrap a pork product, i.e. sausage. The specification discloses that the instant porcine collagen film can be used to form netting, i.e. for trussing pork roast, belly, or ham (p. 7). Morgan et al. also teach that the porcine collagen casing can be used to form netting, i.e. for trussing pork roast, belly, or ham (p. 2 [0022]). Therefore, it would be reasonable for one of ordinary skill to conclude that the porcine collagen casing of Morgan et al. is also a porcine collagen film.

No claim is allowed.



Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marsha M. Tsay whose telephone number is 571-272-2938. The examiner can normally be reached on M-F, 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Kathleen Kerr Bragdon can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

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system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

September 25, 2007

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PRIMARY EXAMINER